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**REMARKS**

The Applicant appreciates the telephone interview initiated by the Examiner on December 5, 2002. During the telephone interview and a subsequent follow-up telephone interview, the Examiner agreed to permit a preliminary amendment prior to Examination.

Claims 2-28 and 48-60 are pending in this application. The claims have been amended in response to a telephone issued restriction requirement by the Examiner. The title also has been amended to be more consistent with the subject matter of the pending claims.

The verbal restriction requirement separated claims into three groups:

- I. Claims 1-17;
- II. Claims 18-28; and
- III. Claims 29-47.

As discussed with the Examiner, to facilitate prosecution of the subject application, Applicant has elected the subject matter in Group II, which includes original claims 18-28. Applicant also has amended claims 2-17 to depend from claim 18, which has been rewritten in independent form.

New claims 48-60 have been added to recite additional aspects of the implant in accordance with an aspect of the present invention as well as to add a related claim set in means-plus-function format.

A substantive examination of the above-identified patent application on its merits is respectfully requested.

Should the Examiner believe that a telephone interview would be helpful to expedite favorable prosecution, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.


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No additional fees should be due for the additional claims in view of the cancellation of other claims from the subject application. In the event any fees are due in connection with the filing of this document, the Commissioner is authorized to charge those fees to our Deposit Account No. 20-0090.

Respectfully submitted,

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**Marked up Version to Show Changes Made****In the Title:**

Please amend the title at page 1, line 1, to read as follows:

[HEART VALVE PROSTHESIS AND SUTURELESS] IMPLANTATION SYSTEM FOR  
[SUTURELESS] IMPLANTATION OF A HEART VALVE PROSTHESIS

**In the Claims:**

Please amend the claims as follows:

2. (Amended) The combination of claim 18 [prosthesis of claim 1], the prosthesis further comprising biasing elements that interconnect at least some of the support features, each biasing element urging support features that are interconnected by respective biasing element apart from each other.
3. (Amended) The combination of claim 2 [The prosthesis of claim 2], the biasing elements further comprising springs arranged in a generally circular array at the opposed ends of the support, the springs interconnecting adjacent support features to bias the support radially outwardly.
4. (Amended) The combination [The prosthesis] of claim 3, the support features and the springs of the prosthesis being formed of a continuous length of a resilient material to provide a cage-like support.
5. (Amended) The combination [The prosthesis] of claim 3, the prosthesis further comprising projections biased to extend radially outwardly from at least one of the opposed ends.
6. (Amended) The combination [The prosthesis] of claim 5, the projections of the prosthesis further comprising a set of triangular projections interconnected at the opposed ends by biasing elements that orient the triangular projections to extend axially and radially outwardly from the respective opposed ends.

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7. (Amended) The combination of claim 18 [The prosthesis of claim 1], the prosthesis further comprising a flexible connecting element attached to the support to inhibit radial outward expansion of at least part of the support beyond a predetermined amount.
8. (Amended) The [prosthesis] combination of claim 7, the connecting element of the prosthesis further comprising a loop of a flexible cord.
9. (Amended) The [prosthesis] combination of claim 7, the prosthesis further comprising a loop of a flexible material connected to the support at each of the opposed ends to inhibit radial outward expansion of the support at the opposed ends beyond a predetermined amount.
10. (Amended) The [prosthesis] combination of claim 18, the support of the prosthesis further comprising at least two generally cylindrical support portions having adjacent ends connected substantially coaxially together, the support portions also having respective spaced apart ends that define the axially opposed ends of the support, the valve including an inflow end and an outflow end spaced apart from each other on axially opposed sides of a juncture between the support portions.
11. (Amended) The [prosthesis] combination of claim 10, the prosthesis further comprising an intermediate connecting element that connects the support portions at the juncture between the support portions.
12. (Amended) The [prosthesis] combination of claim 10, each of the support portions of the prosthesis having a sidewall portion comprising a plurality of elongated support features that extend generally axially between the ends of each respective support portion in a circumferential arrangement, the support features of each support portion being interconnected so as to bias each respective sidewall portion and the valve mounted therein radially outwardly.
13. (Amended) The [prosthesis] combination of claim 12, the prosthesis further comprising a plurality of biasing elements that interconnect adjacent support features in each of

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the support portions, the biasing elements urging the interconnected support features apart from each other to provide radial outward expansion of the respective sidewall portions.

14. (Amended) The [prosthesis] combination of claim 13, the biasing elements of the prosthesis being connected by flexible connecting elements in a generally circular arrangement at the ends of each respective support portion, the connecting elements inhibiting radial expansion of at the respective ends of the support portions beyond a predetermined amount.

15. (Amended) The [prosthesis] combination of claim 12, the prosthesis further comprising projections biased to extend radially outwardly from the axially opposed ends of the support.

16. (Amended) The [prosthesis] combination of claim [14]15, the projections of the prosthesis further comprising a set of triangular projections connected at each of the opposed ends by biasing elements that bias the triangular projections to extend axially and radially outwardly from the respective opposed ends.

17. (Amended) The [prosthesis] combination of claim 18, the prosthesis further comprising an outer sheath of a substantially biocompatible that covers at least a substantial portion of the exposed part of the support.

18. (Amended) [The prosthesis of claim 1] A heart valve prosthesis in combination with an implant, the combination comprising:

the heart valve prosthesis comprising:

a generally cylindrical support extending between opposed ends thereof, a plurality of support features extend generally axially between the opposed ends of the support and are interconnected so as to bias the support radially outwardly; and

a valve mounted within the support to define a supported valve, the supported valve being deformable between a first condition a second condition, the supported valve having a cross-sectional dimension in the second condition that is less than a cross-

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sectional dimension of the supported valve when in first condition, whereby implantation of the supported valve is facilitated when in the second condition;

the implanter including an elongated cylindrical enclosure dimensioned and configured to receive the prosthesis when in the second condition; and

the prosthesis being disposed within the cylindrical enclosure, such that an inner sidewall of the cylindrical enclosure maintains the prosthesis in the second condition.

19. The combination of claim 18, the implanter further comprising a plunger operative to move within the cylindrical enclosure and urge the prosthesis out of the cylindrical enclosure, the support being operative to expand the prosthesis from the second condition to the first condition when discharged from the cylindrical enclosure.

20. An implantation system, comprising:

an elongated cylindrical member having spaced apart ends, at least one of the ends providing an opening;

a heart valve prosthesis including a generally cylindrical support having axially spaced apart ends, a valve mounted within the support at a fixed axial position between the spaced apart ends of the support, the prosthesis being deformable to a first condition in which the prosthesis has a reduced cross-sectional dimension, the support being biased to expand the prosthesis radially outwardly from the first condition to a second condition in which the prosthesis has a cross-sectional dimension that greater than reduced cross-sectional dimension, the prosthesis being mounted within the cylindrical member in the first condition; and

a plunger operative to traverse at least part of the cylindrical member and urge the prosthesis from the cylindrical member through the opening.

21. The system of claim 20, the support being formed of a shape memory alloy operative to urge the prosthesis to the second condition.

22. The system of claim 20, the support further comprising a plurality of elongated support features that extend generally axially between ends of the support, biasing elements interconnecting adjacent support features in a circumscribing relationship around the valve, the

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biasing elements urging the interconnected adjacent support features apart from each other, so as to urge the prosthesis toward the second condition.

23. The system of claim 22, further comprising at least one connecting element operative to hold the biasing elements in a generally circular array and to limit the radial outward expansion of the prosthesis at the location of the circular array.

24. The system of claim 22, further comprising a plurality of resilient projections that extend radially outwardly from the axially opposed ends of the support.

25. The system of claim 24, the projections further comprising a set of triangular projections attached to each of the opposed ends of the support by biasing elements that bias the triangular projections to extend axially and radially outwardly from each of the respective opposed ends of the support.

26. The system of claim 22, the support features and the biasing elements being formed of a continuous length of a substantially resilient and elastic material that facilitates expansion of the prosthesis from the first condition to the second condition.

27. The system of claim 20, further comprising an outer sheath of a substantially biocompatible that covers at least a substantial portion of an exposed part of the support.

28. The system of claim 20 wherein the valve further comprises an animal heart valve.

**Please add the following new claims:**

48. The system of claim 20, further comprising a body portion from which the cylindrical member extends and terminates in the open end.

49. The system of claim 48, the cylindrical member having an inner diameter in a range from about 5 mm to about 15 mm.

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50. The system of claim 48, further comprising a handle portion attached to the body portion at a substantially opposite end from which the cylindrical member extends.

51. The system of claim 48, the cylindrical member being generally linear along its length.

52. The system of claim 51, further comprising indicia along an exterior portion of the cylindrical member to facilitate implantation of the heart valve prosthesis.

53. The combination of claim 18, the implanter further comprising a body portion from which the cylindrical member extends and terminates in the open end.

54. The combination of claim 53, the cylindrical member of the implanter having an inner diameter in a range from about 5 mm to about 15 mm.

55. The combination of claim 53, the implanter further comprising a handle portion attached to the body portion at a substantially opposite end from which the cylindrical member extends.

56. The combination of claim 53, the cylindrical member of the implanter being generally linear along its length.

57. The combination of claim 56, the implanter further comprising indicia along an exterior portion of the cylindrical member to facilitate implantation of the heart valve prosthesis.

58. An implantation system, comprising:  
heart valve means for enabling substantially unidirectional flow of fluid therethrough;



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biasing means for supporting the heart valve means therein and for biasing the valve means from a reduced cross-sectional condition to an expanded cross-sectional condition thereof to facilitate the unidirectional flow of fluid through the heart valve means;

implantation means for retaining the heart valve means and the biasing means in the reduced cross-sectional condition; and

means for discharging the heart valve means from the implantation means through an opening thereof located at a distal end of the implantation means, such that the valve means can expand from the reduced cross-sectional condition to the expanded cross-sectional condition.

59. The implantation system of claim 58, the implantation means further comprising a body generally rigid and substantially linear elongated barrel, the heart valve means being located within a distal end portion of the barrel, the means for discharging further comprising a plunger mechanism operative to traverse the barrel for discharging the heart valve means through an opening of the barrel.

60. The implantation system of claim 59, the heart valve means further comprising a natural tissue animal heart valve.

Please cancel claims 1, and 29-47 without prejudice or disclaimer of subject matter.